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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,374	12/19/2001	John C. Chappell	3383.1	7705

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AFFYMETRIX, INC
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SANTA CLARA, CA 95051

EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/683,374

Applicant(s)

CHAPPELL, JOHN C.

Examiner

BJ Forman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 53-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 53-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7 March 2006 has been entered.

Status of the Claims

2. This action is in response to papers filed 7 March 2006 in which claims 1, 5, 53, 55 and 56 were amended. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 15 September 2005, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1-14 and 53-56 are under prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-14 and 55-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1-4 are indefinite in Claim 1 because the claim is drawn to a method for synthesizing a probe array but the method steps of the claim do not result in array synthesis. Therefore it is unclear whether the method steps accomplish the synthesis as claimed.

Claims 5-14 and 55-56 are indefinite in Claim 5 because the claim is drawn to a method for aligning optical fibers for synthesizing a probe array but the method steps of the claim do not result in array synthesis. Therefore it is unclear whether the method steps accomplish the synthesis as claimed.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 53 is rejected under 35 U.S.C. 102(a) as being anticipated by Braun et al (WO 00/69553, published 23 November 2000) and under 35 U.S.C. 102 (e) as being anticipated by Braun et al (U.S. Patent No. 6,819,843, filed 12 May 2000). The passages of Braun cited below are from the English language translation i.e. U.S. Patent No. 6,819,843.

Regarding Claim 53, Braun et al disclose the array made by the method of Claim 5 (Column 4, line 9-Column 5, line 29). The courts have stated that “even though product-by-process claims are limited by and defined by the process, determination of patentability is

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based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 13, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braun et al (WO 00/69553, published 23 November 2000) and Braun et al (U.S. Patent No. 6,819,843, filed 12 May 2000) in view of Oshida et al (U.S. Patent No. 5,302,999, issued 12 April 1994). The passages of Braun cited below are from the English language translation i.e. U.S. Patent No. 6,819,843.

Regarding Claim 1, 55 and 56, Braun et al disclose a method for synthesizing a nucleic acid probe array comprising providing a substrate, providing photo-protected nucleotides, directing light onto a plurality of optical fibers wherein each fiber operably couples to an interface (i.e. is bundled, Column 5, lines 26-28 and 51-58), selectively switching the elements between light-passing and non-passing in response to gating data whereby a set of fibers is in the light-passing state (i.e. “light is coupled to the fiber, the light exiting at the end precisely illuminated the corresponding grid point, Consequently the number of optical fibers that are

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necessary corresponds precisely to the grid points that are provided", Column 4, line 62-Column 5, line 28), disposing light thorough the set of optical fibers onto each aligned area of the substrate (Column 5, lines 2-28) to provide a reactive group and contacting the nucleotides with the reactive group (Column 4, lines 24-37 and Claim 17).

Braun et al specifically teach bundled fibers (Column 5, lines 26-28 and 51-58) wherein the bundled fibers are precisely positioned adjacent the substrate for synthesis reactions. The bundles and positioning taught by Braun et al clearly suggest that the fibers are disposed within a structure for facilitating mechanical alignment. However, the reference does not specifically teach an interface element.

Braun et al further teach the importance of specific arrangements and bundling of the fibers "geometrical packing represents the most essential advantage of the invention." (Column 5, lines 51-57) but they are silent regarding an interface comprising wells having walls operatively coupled with the tapered ends of the fibers. However, optical fibers coupled to an interface having tapered wells complementary to tapered fibers was known in the art at the time the claimed invention was made as taught by Oshida et al (Fig. 2 and 11). Oshida et al teach a method of aligning optical fibers wherein the fibers are bundled within a mechanism (#10) to provide desired positioning of fibers within the bundle resulting light being directing as desired (Column 10, lines 35-40 and Column 12, lines 25-37). To provide the desired bundle, the fibers are arranged in a welled structure complementary to tapered fibers whereby a desired divergent angle of light is provided without the use of lens (Column 12, lines 25-37 and Fig. 11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the welled structure of Oshida et al to the geometrically packaged fibers of Braun et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success for the expected benefit of providing the desired divergent angle of light without the use of lens as taught by Oshida et al (Column 12, lines 25-37 and Fig. 11).

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Regarding Claim 2, Braun et al disclose the method wherein light passed through at least one fiber in the light-passing state to strike each aligned area of the substrate thereby activating the area i.e. grid point (Column 3, line 63-Column 4, line 8 and Column 5, lines 2-9).

Regarding Claim 3, Braun et al disclose the method wherein the light includes ultraviolet (Column 3, lines 23-34).

Regarding Claim 4, Braun et al disclose the method wherein the plurality of optical fiber elements comprises an optical fiber (a bundle of optical fibers, Column 3, lines 25-27).

Regarding Claim 5, Braun et al disclose a method for aligning optical fibers with a area for probe synthesis on a substrate comprising, directing light onto a plurality of optical fibers wherein each fiber operably couples to an interface (e.g. mask) that aligns an end of the fiber with a synthesis area on the substrate (Column 5, lines 35-47), selectively switching the optical fibers between light-passing and non-passing in response to gating data (i.e. controlled exposure pattern, Column 4, line 58-Column 5, line 57) and disposing light through optical fibers onto the substrate (Column 3, line 57-Column 4, line 38 and Claim 17).

Braun et al specifically teach bundled fibers (Column 5, lines 26-28 and 51-58) wherein the bundled fibers are precisely positioned adjacent the substrate for synthesis reactions. The bundles and positioning taught by Braun et al clearly suggest that the fibers are disposed within a structure for facilitating mechanical alignment. However, the reference does not specifically teach an interface element.

Braun et al further teach the importance of specific arrangements and bundling of the fibers "geometrical packing represents the most essential advantage of the invention." (Column 5, lines 51-57) but they are silent regarding an interface comprising wells having walls operatively coupled with the tapered ends of the fibers. However, optical fibers coupled to an interface having tapered wells complementary to tapered fibers was known in the art at the time the claimed invention was made as taught by Oshida et al (Fig. 2 and 11). Oshida et al teach a method of aligning optical fibers wherein the fibers are bundled within a mechanism

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(#10) to provide desired positioning of fibers within the bundle resulting light being directing as desired (Column 10, lines 35-40 and Column 12, lines 25-37). To provide the desired bundle, the fibers are arranged in a welled structure complementary to tapered fibers whereby a desired divergent angle of light is provided without the use of lens (Column 12, lines 25-37 and Fig. 11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the welled structure of Oshida et al to the geometrically packaged fibers of Braun et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success for the expected benefit of providing the desired divergent angle of light without the use of lens as taught by Oshida et al (Column 12, lines 25-37 and Fig. 11).

Regarding Claim 6, Braun et al disclose the method further comprising activating each aligned area of the substrate (Column 3, line 62-Column 4, line 8 and Column 5, lines 2-9).

Regarding Claim 7, Braun et al disclose the method wherein light passed through each fiber strikes an aligned area thereby activating the area (Column 3, line 63-Column 4, line 8 and Column 5, lines 2-9).

Regarding Claim 13, Braun et al disclose the method further comprising deactivating the areas (i.e. light to the selected portion is turned off, masked or blocked, and building blocks for chain elongation are added, Column 3, lines 62-67 and Column 4, line 58-Column 5, line 57).

8. Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braun et al (WO 00/69553, published 23 November 2000) and Braun et al (U.S. Patent No. 6,819,843, filed 12 May 2000) in view of Oshida et al (U.S. Patent No. 5,302,999, issued 12 April 1994) as

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applied to Claim 5 above and further in view of Adams et al (U.S. Patent No. 6,156,494, filed 28 October 1997).

Regarding Claim 8, Braun et al disclose a method for synthesizing a nucleic acid probe array comprising providing a substrate, providing photo-protected nucleotides, directing light onto a plurality of optical fibers wherein each fiber operably couples to an interface (e.g. mask) that aligns an end of the fiber with a synthesis area on the substrate (Column 5, lines 35-47), selectively switching the elements between light-passing and non-passing in response to gating data whereby a set of fibers is in the light-passing state (i.e. controlled exposure pattern, Column 4, line 58-Column 5, line 57), disposing light thorough the set of optical fibers onto each aligned area of the substrate to provide a reactive group and contacting the nucleotides with the reactive group (Column 3, line 57-Column 4, line 38 and Claim 17).

Braun et al teach the method wherein reagents, including nucleic acid building blocks for chain elongation, are added to the support (Column 3, line 62-column 4, line 8) and they define the building blocks as monomers bearing functional groups (Column 1, lines 59-67) but they are silent regarding providing linkers on the substrate. However, linkers were well known in the art of nucleic acid synthesis as taught by Adams et al (Column 6, lines 31-39). Adams teaches a similar method arrays comprising, directing light onto one or more optical transfer elements, selectively switching the elements between light-passing and non-passing and disposing light thorough optical transfer element onto the substrate (Column 5, lines 13-48 and Claims 1 and 27-29) wherein linkers are means for functionalizing the support for nucleic acid attachment (Column 6, lines 13-41). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the support of Braun et al with the linkers taught by Adams et al for the expected benefit of providing a means for nucleic acid attachment as taught by Adams et al (Column 6, lines 13-48).

Regarding Claim 9, Braun et al teach the method wherein reagents, including nucleic acid building blocks for chain elongation, are added to the support (Column 3, line 62-column

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4, line 8) and they define the building blocks as monomers bearing functional groups (Column 1, lines 59-67).

Regarding Claim 10, Braun et al teach the method wherein chain-elongating building blocks are added and they define the building blocks for nucleic acid synthesis include nucleotides (Column 1, lines 59-67).

Regarding Claim 11, Braun et al teach the method wherein the monomers include photoremovable protective groups i.e. "a light source emits a spectrum of wavelengths that can effect the deprotection of the nucleotides" (Column 3, lines 62-67). And Adams et al disclose the method wherein the monomer includes a photo-removable protecting group (e.g. Column 12, lines 12-26).

Regarding Claim 12, Braun et al teach the method further comprising selectively switching the elements between light-passing and non-passing in response to gating data whereby a set of fibers is in the light-passing state (i.e. controlled exposure pattern, Column 4, line 58-Column 5, line 57) and adding chain-elongating building blocks (Column 3, line 62-column 4, line 8) and they define the building blocks as monomers bearing functional groups (Column 1, lines 59-67). And Adams et al disclose the method wherein light passed though at least one optical transfer element strikes a second set of selected portions thereby activating the portions and contacting with a second monomer (Column 5, lines 13-48 and Claims 27-29).

Regarding Claim 13, Braun et al disclose the method further comprising deactivating the areas (i.e. light to the selected portion is turned off, masked or blocked, and building blocks for chain elongation are added, Column 3, lines 62-67 and Column 4, line 58-Column 5, line 57). And Adams et al disclose the method further comprising deactivating selected portions (i.e. at step (d) light activations forms a covalent bond between the first immobilized component and second component, Claim 1, step (d)).

Regarding Claim 14, Adams et al disclose the method wherein light passed through the transfer element, strikes a portion to deactivate the portion (i.e. at step (d) light activations

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forms a covalent bond between the first immobilized component and second component, Claim 1, step (d).

9. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Braun et al (WO 00/69553, published 23 November 2000) and Braun et al (U.S. Patent No. 6,819,843, filed 12 May 2000) in view of Oshida et al (U.S. Patent No. 5,302,999, issued 12 April 1994) as applied to Claim 5 above and further in view of Schembri et al (U.S. Patent No. 6,518, 056, filed 27 April 1999).

Regarding Claim 54, Braun et al teach the array made by the method of Claim 5 (Column 3, line 57-Column 4, line 38 and Claim 17) but they do not teach using customer-specific data to produce the arrays. However, custom-made arrays made according to customer specified data was well known in the art at the time the claimed invention was made as taught by Schembri et al who specifically teach this facilitates "experiment on demand" research (Column 15, lines 52-63). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the customer data taught by Schembri et al to the arrays of Adams et al for the economy of experiment-specific array production and facilitation of manufacturing as taught by Schembri et al (Column 15, lines 33-35 and 52-63).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

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Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,685,655. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of probe array synthesis using optical fibers to illuminate synthesis sites. The claim sets merely differ in the arrangement of limitations within the claim sets and terminology used to describe certain elements. For example, instant claims 1 and 14 are drawn to an interface element that aligns the optical fiber while the '655 claim set defines the alignment as a translation across the substrate. However, the instantly claimed element for mechanical alignment would have been obvious because absent some mechanics, the patent translation could not occur.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

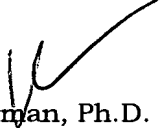
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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
May 2, 2006